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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,384	01/30/2006	Brian Frostrup	2815-0347PUS1	5532

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BIRCH STEWART KOLASCH & BIRCH  
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FALLS CHURCH, VA 22040-0747

EXAMINER
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RODRIGUEZ-GARCIA, VALERIE

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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12/01/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,384	<b>Applicant(s)</b> FROSTRUP ET AL.	
	<b>Examiner</b> VALERIE RODRIGUEZ-GARCIA	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-23 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

VRG 11/19/08

## DETAILED ACTION

### *Status of the Claims*

Receipt of the remarks, amendments and affidavit (Rule 132) filed on 10/10/08 is acknowledged. Pursuant to amendment, claims 13-23 are pending. Claims 13-15 and 20 are the subject of this Office Action.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-15 and 20 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Scheel-Kruger *et al.* (US 6,288,079B1) as evidenced by Berge *et al.* (J. Pharm. Sci. 1977; 66(1);1-19) for reasons of record and those discussed below.

Applicant's arguments are responded to below.

1. The affidavit under 37 CFR 1.132 filed 10/10/08 is insufficient to overcome the rejection of claims 13-15 and 20 based upon 35 U.S.C. 103(a) as being unpatentable over Scheel-Kruger *et al.* (US 6,288,079B1) as evidenced by Berge *et al.* (J. Pharm. Sci. 1977; 66(1);1-19) as set forth in the last Office action: A person of ordinary skill in the chemical or pharmaceutical arts would have envisioned to make the tartrate salt of the claimed compound from the 079 reference with expectation of reasonable success, because there are only a finite number of pharmaceutically acceptable salts disclosed in

079 and the tartrate salts are also the 4<sup>th</sup> most commonly commercially marketed salts approved by the FDA as seen in Berge *et al.*. Please, see Pfizer, Inc. v. Apotex, Inc., 82USPQ2d 1321 (Fed. Cir. 2007) as it strongly relates to this case. *Unexpected results of improved properties of the claimed salt were not sufficient to hold the patent valid, where there were only a finite number (53) of pharmaceutically acceptable salts to be tested for improved properties. Claims 1-3 of the Pfizer patent were found invalid for obviousness.*

### ***Response to Arguments***

Applicants' arguments have been fully considered, but are not found persuasive. Applicants argue that the examiner did not appropriately resolved the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) for the obviousness analysis and that the rationale the examiner provides for combining the reference is improper. Applicants also argue that the examiner bases his assertions on hindsight reconstruction.

The Graham factors were discussed in the previous action. US 6,288,079B1 (079) reference discloses a finite number of salts of (1R, 2R, 3S, 5S)-2-methoxymethyl-3-(3,4-dichlorophenyl)-8-azabicyclo[3.2.1]octane including the tartrate salt and how they can be formed by procedures well known in the art (column 5, lines 24-30). For clarification purpose, the 079 reference suggests the instantly claimed invention though not as the preferred embodiment. Berge reference is used as additional evidence of how common tartrate salts are in the pharmaceutical arts. A person of ordinary skill in

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the chemical and pharmaceutical arts (which would have a bachelors and some working experience in the art) would envision making the tartrate salt of the invention due to the suggestion of the 079 reference alone and will find reassurance in Berge's reference. Hindsight reconstruction was not applied because the invention was fully suggested by 079 reference.

**Note:** As applicants remark, WO 97/30997 is equivalent to US 6,288,079B1.

### **Conclusion**

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone

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number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Kamal A Saeed/

Primary Examiner, Art Unit 1626